

**RCT on the Management of Early Pregnancy Failure  
SCREENING LOG INSTRUCTIONS (FORM 16)**

**GENERAL INSTRUCTIONS**

This form is completed in each Clinical Site for all pregnant women who are screened and not randomized into the trial. The required information for each patient is recorded on this form as soon as possible after screening of the patient has been completed. The completed form is sent by mail or e-mail to the Data Center.

**A. ETHNIC ORIGIN**

**ETHNICITY**

Hispanic or Latino. A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

**RACE**

- 1 American Indian or Alaska Native. A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
- 2 Asian. A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- 3 Black or African American. A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
- 4 Native Hawaiian or Other Pacific Islander. A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- 5 White. A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

**B. INCLUSION CRITERIA**

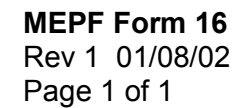
List the first inclusion letter (A-E) that is not satisfied that makes the patient ineligible. If none record X.

- A Early pregnancy failure
- B Willing to accept randomization
- C Willing to comply with the study protocol and follow-up visit schedule
- D Access to telephone and able to provide detailed contact information
- E Adequate venous access for phlebotomy

**C. EXCLUSION CRITERIA**

List the first exclusion letter (A-M) that makes the patient ineligible. If none record X.

- A Orthostatic hypotension
- B Ovarian hyperstimulation Syndrome
- C Contraindication to misoprostol use
- D Surgical or medical abortion for the current pregnancy prior to enrollment
- E Known or expected ectopic pregnancy
- F Known or suspected pelvic infection
- G Hemoglobin < 9.5 mg/dL
- H Known clotting disorder or use of anticoagulants
- I Cardiovascular disease
- J Current breast feeding
- K Mental conditions or circumstances that are deemed unsuitable for participating in the study
- L Karyotyping of fetal tissue is required
- M Concurrent participation in any other intervention trial



## SCREENING LOG

**CLINICAL SITE NUMBER AND NAME:** \_\_\_\_\_ **BEGIN SCREEN DATE** \_\_\_\_\_ **END SCREEN DATE** \_\_\_\_\_

[illegible]